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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,494	11/02/2000	Timothy Samuel Girton	760-35	4895

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/704,494	Applicant(s) GIRTON, TIMOTHY SAMUEL	
	Examiner Cheryl L. Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract is too short in length and is required to be more descriptive and lengthened to between 50 and 150 words.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "12" has been used to designate both "the stent" and "the outer surface". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The error was found to occur on page 5 of the specification.

3. Figure 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "10" and "12" have both been used to designate "the stent". A proposed drawing correction or

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The error was found to occur on pages 6 and 8 of the specification.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 11 and 13. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The error was found to occur on pages 6 and 8 of the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 7 recites the limitations "said inner surface", "said exterior surface", and "the longitudinal stent axis" in line 6, line 6, and line 7 respectively. There is insufficient antecedent basis for these limitations in the claim. It is suggested to change "said inner surface" to recite --an inner surface--, to change "said exterior surface" to recite --an exterior surface--, and to change "the longitudinal stent axis" to recite --a longitudinal stent axis--.

Claim Objections

9. Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

It is common knowledge in the art that non-stretched polytetrafluoroethylene has an absence of node and fibril structure.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Chouinard (USPN 6,156,064). Chouinard discloses an endoprosthesis, which includes all limitations recited in the claims. Chouinard discloses a radially expandable tubular stent and stent cover (col.1, lines8-12; col.2, lines45-47; col.3, lines29-33), the stent having an interior and an exterior surface (col.2, lines41-44) and a porous non-stretched polytetrafluoroethylene stent cover (col.2, lines62-67; col.3, lines1-3, 48-50) on both interior and exterior surfaces (col.3, lines24-29).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. In the alternative to the above rejection, claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chouinard in view of Dillon (USPN 6,235,377 B1). Chouinard discloses the invention substantially as claimed (see above rejection). Chouinard discloses a polytetrafluoroethylene non-expanded (meaning no nodes or fibrils) stent cover (col.3, lines1-3, 48-50). Chouinard does not however, explicitly disclose the absence of nodes and fibrils in the polytetrafluoroethylene. However, Dillon teaches formation of nodes and fibrils caused by stretching or expansion (col.2, lines1-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of node and fibril formation by stretching, with Chouinard's non-stretched stent cover, in order to not stretch the polytetrafluoroethylene, to prevent the formation of nodes and fibrils.

14. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chouinard (USPN 6,156,604) in view of Dillon (USPN 4,945,125 as cited in applicants IDS) and in further view of McCollam et al. (USPN 6,143,675). Chouinard discloses the invention substantially as claimed. Referring to claim 1, Chouinard discloses an endoprosthesis (col.2, lines37-38) comprising a radially expandable tubular stent (col.2, lines21, 46-47) having an interior surface and an exterior surface extending along a longitudinal axis (col.2, lines41-44). Chouinard discloses a porous stent cover (col.2, lines61-67) formed of a polytetrafluoroethylene material (col.3, line1-3, 44-50). Chouinard discloses a stent cover located on an exterior and an interior surface of a stent (fig.3; fig.6; col.2, lines52-57) as claimed in claim 2. Chouinard discloses an expandable stent cover (col.3, lines29-34; col.11, lines5-7) as

claimed in claim 3. Chouinard discloses a porous stent cover formed of siloxane and polytetrafluoroethylene (col.9, lines14-19) as claimed in claim 1, wherein the siloxane is chemically extracted (col.9, lines26-28, 41-43; col.10, lines15-18) as claimed in claim 4, and heat extracted (col.9, lines46-48; col.10, lines19-24) as claimed in claim 6.

Chouinard however, does not disclose formation of an interpenetrating network with siloxane and polytetrafluoroethylene, nor does Chouinard disclose removal of siloxane at a temperature of at least 300°C. McCollam teaches formation of a porous composite comprising polytetrafluoroethylene (col.1, lines1-8) and a collagen, the polytetrafluoroethylene being heated to a temperature above 300° (col.2, line65-67; col.3, lines18-23) in order to form pores. McCollam does not disclose however, siloxane to be combined with the polytetrafluoroethylene. Dillon teaches formation of a siloxane/polytetrafluoroethylene interpenetrating network for the purpose of having a porous product with increased strength (col.2, lines48-53; col.3, lines1-8; col.6, lines15-18; col.7, lines35-38). Dillon teaches siloxane removal by chemical and heat applied to an IPN at a temperature above 300°C for the purpose of curing the siloxane (col.5, lines63-65; col.7, lines32-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine McCollam's teaching of heating a composite to form pores, with Dillon's teaching of siloxane/polytetrafluoroethylene IPN formation with high temperature heating, with Chouinard's siloxane/polytetrafluoroethylene stent cover in order to cure the siloxane and form a porous stent cover.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chouinard (USPN 6,156,604) in view of Dillon (USPN 4,945,125 as cited in applicants IDS) and in further view of McCollam et al. (USPN 6,143,675) and in further view of Kipke et al. (Pub. No. US2001/0031978A1). Chouinard in view of Dillon in further view of McCollam disclose the invention substantially as claimed. Chouinard in view of Dillon in further view of McCollam disclose extraction by a chemical (Chouinard col.9, lines26-28, 41-43; col.10, lines15-18) however, do not disclose the chemical being toluene,

heptane, or chloroform. Kipke teaches the use of chloroform for the purpose of extracting a material from a composite (0011, 0038, 0048, 0050). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kepke's teaching of chloroform used as an extractor, with the chemical extraction method of Chouinard in view of Dillon in further view of McCollam in order to extract siloxane from a composite (IPN) with chloroform.

16. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chouinard (USPN 6,156,064) in view of Dillon (USPN 4,945,125 as cited by applicant in IDS). Chouinard discloses the invention substantially as claimed. Chouinard discloses a radially expandable tubular stent (col.2, lines45-47), and a porous polytetrafluoroethylene stent cover for an interior and an exterior surface of a stent (col.3, lines1-3, 24-29, 48-50). Chouinard discloses use of an adhesive to fix the stent cover to the stent (col.3, lines55-56; col.4, lines44-48).

Chouinard does not disclose however, a process of forming an interpenetrating network of siloxane and polytetrafluoroethylene. Dillon teaches formation of a siloxane/polytetrafluoroethylene interpenetrating network for the purpose of forming a porous structure with increased strength (col.2, lines47-50; col.6, lines16-19; col.7, lines35-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of method of making a siloxane/polytetrafluoroethylene interpenetrating network with Chouinard's siloxane/polytetrafluoroethylene stent cover in order to form a porous cover with increased strength.

17. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chouinard in view of Dillon as applied to claim 7 above, and further in view of Edwin et al. (USPN 6,053,943). Chouinard in view of Dillon disclose the invention substantially as claimed. Chouinard in view of Dillon does not however, disclose fixation by a particular adhesive, or fixation by welding. Edwin teaches a radially expandable stent having a stent cover (col.2, lines52-55; col.3, lines14-17) adhered to stent by an adhesive selected from the group consisting of polyurethane's, epoxies, cyanoacrylates, polyamidies,

polyimides, and silicones (col.8, lines26-29) in order to bond the stent to the stent cover. Edwin teaches a method of bonding the stent to the stent cover by welding at a temperature above polytetrafluoroethylene's sintering temperature (col.9, lines54-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of use of a particular adhesive or welding at a temperature above the sintering temperature in order to bind the stent to the stent cover.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCollam et al (USPN 6,143,675) in view of Dillon (USPN 5,980,923 as cited by applicant in IDS). McCollam discloses the invention substantially as claimed. McCollam discloses a method of producing a porous polytetrafluoroethylene tube used in medical devices (fig.3, 4; col.1, lines1-8) by combining polytetrafluoroethylene with a second material, removing the second material (col.3, lines2-8) and leaving a porous polytetrafluoroethylene structure (col.2, line67; col.9, lines49-51; col.10, lines4-8). McCollam discloses the second material as being a collagen and does not disclose material as being siloxane nor formation of an interpenetrating network. Dillon teaches formation of an interpenetrating network between siloxane and polytetrafluoroethylene (col.3, lines33-35, 49-53) in order to increase strength and elasticity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dillon's teaching of IPN formation with siloxane, with McCollam's method of forming a porous polytetrafluoroethylene structure in order to increase strength and elasticity.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 5,693,085 to Buirge et al. discloses a stent with a stent cover bonded to it by welding, wherein welding is defined as application of heat and pressure.

USPN 4,533,369 to Okita discloses a porous PTFE/siloxane composite wherein high temperatures and pressure remove the siloxane, resulting in a porous structure.

USPN 5,769,884 to Solovay discloses porous coating for a stent, wherein the coating is made of PTFE and silicone and pores are made by dissolving coating with a chemical solvent.

USPN 6,245,099 to Edwin et al. discloses a stent having an inner and outer coating made of non-expanded porous PTFE, wherein the layers are bonded to the stent by an adhesive or by a welding and sintering process.

JP 06116774A to Furuya discloses mixing PTFE with a surfactant and removal of the surfactant chemically with toluene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl L. Miller
03/19/2002

DINH X. NGUYEN
PRIMARY EXAMINER